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Dated: April 23, 2003

Signature: 
(Monica L. Thomas)

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Docket No.: HO-P02102US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Suzanne Fuqua, et al

Application No.: 10/052,092

Group Art Unit: 1632

APR 28 2003

TECH CENTER 1600/2900

Filed: January 18, 2002

Examiner: Bertoglio, Valarie

For: **METHODS AND COMPOSITIONS IN
BREAST CANCER DIAGNOSIS AND
THERAPEUTICS**

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action mailed March 26, 2003.

The Examiner has required restriction between the following Groups:

Group I: Claim 1, drawn to a nucleic acid with an A908G mutation;

Group II: Claim 2, drawn to a polypeptide with a K303R substitution;

Group III: Claims 3-10, 12-14, 16-20, and 22, drawn to a method of detecting breast cancer using a nucleic acid assay and a kit comprising a nucleic acid primer for carrying out said method;

Group IV: Claims 3-9, 11-13, 15, 16-19, 21, and 24, drawn to a method of detecting breast cancer using immunoassay to detect an A908G mutation in an estrogen receptor alpha nucleic acid and a monoclonal antibody designed to bind an estrogen receptor alpha nucleic acid comprising an A908G mutation;

Group V: Claim 23, drawn to a monoclonal antibody that binds an acetylated estrogen receptor alpha polypeptide;

Group VI: Claims 25-32, drawn to a method of in vivo gene therapy to correct a G

mutation at nucleotide 908 of the estrogen receptor alpha nucleic acid sequence;

Group VII: Claims 33 and 34, drawn to a method of in vivo protein therapy to prevent breast cancer comprising administering a polypeptide comprising an estrogen receptor alpha sequence comprising a lysine residue at amino acid 303;

Group VIII: Claim 35, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vitro by admixing the candidate modulator with a compound or cell;

Group IX: Claim 35, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vivo;

Group X: Claims 36-44, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vitro using recombinant cells comprising a vector encoding mutant estrogen receptor alpha K303R polypeptide and a vector comprising an estrogen-responsive regulatory element operably linked to a reporter polynucleotide;

Group XI: Claims 45 and 53, drawn to a method of treating breast cancer using an antagonist of a mutant estrogen receptor alpha K303R polypeptide;

Group XII: Claims 46-52, drawn to an in vitro method of identifying a polypeptide that interacts with an estrogen receptor alpha K303R polypeptide comprising introducing into a cell a vector comprising a chimeric estrogen receptor alpha K303R polypeptide and a DNA binding domain and a vector comprising a polynucleotide encoding a chimeric comprising a candidate polypeptide and a DNA activation domain;

Group XIII: Claims 54-56, drawn to an in vitro method of identifying a polypeptide that interacts with an estrogen receptor alpha K303R polypeptide comprising obtaining an affinity tagged estrogen receptor alpha K303R polypeptide, introducing said polypeptide to a plurality of bacteriophage that produce polypeptides and determining binding;

Group XIV: Claims 57-59, drawn to an in vivo method of identifying a compound for treatment of breast cancer;

Group XV: Claims 60-61, drawn to a compound having therapeutic activity for the treatment of breast cancer; and

Group XVI: Claims 62-63, drawn to a transgenic mouse comprising an estrogen receptor alpha having an A908G mutation.

Applicant hereby provisionally elects without traverse and without prejudice and acquiescence Group III having claims 3-10, 12-14, 16-20, and 22 for continued examination. Applicants reserve the right to pursue non-elected claims in other prosecution.

The Examiner furthermore set forth allegedly patentably distinct species for the claimed invention, namely Group A-G and Group H-X, and requested Applicants to elect a single disclosed species from each of these groups. Applicants contacted the Examiner in a telephonic interview of April 17, 2003 and requested clarification of these instructions. The Examiner clarified that it was not necessary to elect a species from a species Group if the claims were not directed to that element. Applicants thank the Examiner for her time and consideration.

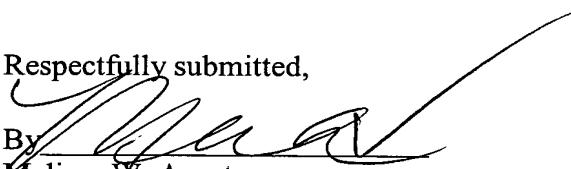
Pursuant to the Examiner's requirement, Applicants elect SEQ ID NO:15 as a species for prosecution on the merits pursuant to the claims of Group III.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02102US2 from which the undersigned is authorized to draw.

Dated: 04/23/03

Respectfully submitted,

By


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Melissa L. Sistrunk

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APR 23 2003

Total Number of Pages in This Submission

4

Application Number	10/052,092
Filing Date	January 18, 2002
First Named Inventor	Suzanne Fuqua
Group Art Unit	1632
Examiner Name	V. Bertoglio

1632

Attorney Docket Number HO-P02102US2

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below)
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Postcard
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
	Remarks	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

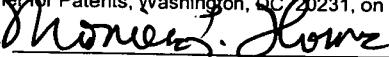
Firm or Individual Name	FULBRIGHT & JAWORSKI L.L.P. Melissa W. Acosta
Signature	
Date	April 23, 2003

Transmittal

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